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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,131	08/21/2003	Ponnappakkam Adikesavan Loka Bharathi	64682-Z/JPW/FHB	7112
7590	11/30/2004		EXAMINER	DAVIS, RUTH A
John P. White Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/645,131	BHARATHI ET AL.
	Examiner Ruth A. Davis	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 27 September 2004.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10 and 13-19 is/are pending in the application.  
 4a) Of the above claim(s) 6-10 and 13-19 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-5 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1 – 5 in the reply filed on September 27, 2004 is acknowledged. The traversal is on the grounds that the inventions are not independent and that there is not a burden of search. This is not found persuasive because the instant claims are drawn to both independent and distinct inventions, because they have different functions, effects and modes of operation. One would not have to practice the various inventions together to practice just one alone. In addition, as serious burden on examiner has been established since each of the groups are classified in separate classifications classes and/or subclasses, which would require separate searches. Applicant is reminded that an overlapping search is not a coextensive search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6 – 10 and 13 – 19 are withdrawn from further consideration, as being drawn to non-elected subject matter. Claims 1 – 5 have been considered on the merits.

***Specification***

2. The disclosure is objected to on page 8, lines 7 – 8, for reciting “International depository.....having accession no.....,“.

Also, page 8, line 14, “caratenoid” should be spelled “carotenoids.

Correction is required.

***Claim Objections***

3. Claims 3 and 4 are objected to because of the following informalities:

In claim 3, line 5, the term “caratenoid” should be spelled correctly as “carotenoid”.

In claim 4, line 2, “laving” should be spelled correctly as “having”.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 – 5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The instant claims are drawn to a deep sea bacterium found in nature. The claims do not suggest or recite any limitations to indicate the instant bacterium is a “naturally occurring manufacture or composition of matter – a product of human ingenuity – having a distinctive name, character, [and] use” (MPEP 706.03(a)B and 2105).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1 – 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a deep sea bacterium, which is identified solely by an accession number and the depth at which the bacteria was collected from the Indian Ocean. The specification fails to set forth any identifying taxonomic, structural, physical or functional characteristics possessed by the bacterium. While the specification states that the bacterium has “similar properties to *Brevibacterium casei*”, the specification fails to identify what theses properties are, how they are similar and/or how they differ. Other than identifying where in the world one might be able to locate the bacteria, the specification fails to describe in such full, clear, concise and exact terms so as to indicate that Applicant had possession of the claimed bacterium at the time of filing the present application.

While Applicant may show possession of the claimed bacterium by describing a deposit made in accordance with 37 CFR 1.801 or by reference to a deposit, such a deposit is not a substitute for a written description. “The specification must be sufficient to permit verification that the deposited biological material is in fact that disclosed.” (Id. at 34,880, MPEP 2163) The written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description (MPEP 2163(I)).

7. Claims 1 – 5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 – 5 are drawn a deep sea bacterium, disclosed as a deep sea bacteria found in the coastal zone of Arabian Sea, Goa, India with properties similar to *Brevibacterium casei* (specification p.7). However, the specification does not disclose a repeatable process to obtain the microorganism required and it is not apparent if the microorganism is readily available to the public. Applicant does not describe any taxonomic, structural, physical or functional characteristics possessed by the specific bacterium that is claim designated. Moreover, the generic statement, “which has a similar properties to known *Brevibacterium casei*” without more, does not provide the identifying characteristics of the bacterium or an extract thereof. Other than identifying where in the world one might be able to locate the bacteria, the specification does not provide any teachings as to what relevant identifying characteristics exist to establish the bacterium used in the claimed invention. Absent of such teachings and guidance as to the identifying characteristics of the bacteria, or of the petroleum and alcoholic extracts thereof, the specification is lacking critical information which would enable one skilled in the art to prepare, reproducibly and consistently, make or use the invention. The specification does not provide information by which one can identify the bacteria to be extracted to obtain the claimed composition.

Since the microorganism is recited in the claims, it is essential to the invention recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, a deposit of the microorganism may satisfy the requirements of 35 U.S.C. § 112. However it is reiterated that a deposit alone is not a substitute for written description or enablement. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. Moreover, because no taxonomic information appears in the specification, it is not clear what the microorganism actually is.

It appears that a deposit was made in this application as filed as noted on page 8 of the specification. However, it is unclear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C. § 112, first paragraph, in the following manner.

#### SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.
2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
3. States that the deposited material has been accorded a specific (recited) accession number.
4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1 – 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 – 5 are drawn to a deep sea bacterium, however are rendered vague and indefinite because it is unclear what applicant intends are the claimed subject matter. While the claims recite a depository accession number, neither the claim language nor specification set forth an adequate description or definition of the scope of the invention in such a way that it is clear what bacterium is being claimed.

Claim 1 and its dependents are rendered vague and indefinite for reciting “Type Culture Collection and Gene Bank” because it is unclear if applicant intends the phrase to read “Microbial Collection and Gene Bank”, as this appears to be the actual name of the depository MTCC.

Claim 1 and its dependents are drawn to a bacterium, however are rendered vague and indefinite because it is unclear if the claimed bacteria is isolated from the deep sea at 5000m, or if *B. casei* is isolated from the deep sea at 5000m.

The claims are further indefinite for reciting “similar properties to known *Brevibacterium casei*” because the claim language and specification fail to define what “similar properties” exist, or what the properties are.

Claim 2 is confusing for reciting “on i.e. it” because it is unclear if the phrase that follows is intended as a further limitation.

In claim 3, lines 2 and 5, “the petroleum ether fraction” and “the carotenoid compound” lacks sufficient antecedent basis.

In claim 4, line 2 “the alcoholic extract” lacks sufficient antecedent basis.

Claim 4 is rendered indefinite because it is unclear if the disclosed properties are of the bacteria itself or of an extract of the bacteria. Moreover, it is unclear if the claim is to (a) an

alcoholic extract of a bacteria, or (b) to a bacteria whose alcoholic extracts has the claimed properties.

In claim 5, line 2, “the extract” lacks sufficient antecedent basis.

Claim 5 is rendered vague and indefinite for reciting “many industrial applications” because the claim language or specification fail to adequately define what the “many industrial applications” include or exclude.

Claim 5 is further indefinite for reciting “such as” because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 5 is rendered vague and indefinite for reciting “colour cum preservative” because the phrase is not adequately defined by the claim language or specification.

#### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 – 5 are rejected under 35 U.S.C. 102(b) as being unpatentable over Funke et al. (1996).

Applicant claims a deep sea bacterium with similar properties to *Brevibacterium casei*. The bacterium is baroduric; petroleum ether extracts exhibit specific spectrometer readings;

alcohol extracts of the bacterium exhibit carotenoids, UV absorption, antibacterial and pH indicating properties; and the bacterium is used as a food or beverage additive.

Funke teaches *Brevibacterium casei* bacteria, defined in 1983, and various properties of the bacterium (p. 27874-7).

Since applicant specifically states that the bacterium of the invention has similar properties to that of *B. casei*, and does not provide any other properties to the claimed bacterium, the strains appear to be the same. Therefore, while Funke does not teach that the bacterium is baroduric or that extracts of *B. casei* exhibit the claimed properties, such properties would be intrinsic to the disclosed bacteria. See also, *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) (“the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product”).

Although Funke does not teach the bacterium can be used in the manner instantly claimed, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting.

The reference discloses a strain that appears to be identical to the presently claimed strain. Consequently, the claimed strain appears to be anticipated by the aforementioned reference.

12. Claims 1 – 5 are rejected under 35 U.S.C. 102(b) as being unpatentable by Rozzell, Jr. (US 5885767 A).

Applicant claims a deep sea bacterium with similar properties to *Brevibacterium casei*. The bacterium is baroduric; petroleum ether extracts exhibit specific spectrometer readings; alcohol extracts of the bacterium exhibit carotenoids, UV absorption, antibacterial and pH indicating properties; and the bacterium is used as a food or beverage additive.

Rozzell teaches a deposited *Brevibacterium casei* bacterium and various properties thereof (col.13).

Since applicant specifically states that the bacterium of the invention has similar properties to that of *B. casei*, and does not provide any other properties to the claimed bacterium, the strains appear to be the same. Therefore, while Rozzell does not teach that the bacterium is baroduric or that extracts of *B. casei* exhibit the claimed properties, such properties would be intrinsic to the disclosed bacteria. See also, *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433

(CCPA 1977) (“the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product”).

Although Rozzell does not teach the bacterium can be used in the manner instantly claimed, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting.

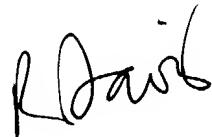
The reference discloses a strain that appears to be identical to the presently claimed strain. Consequently, the claimed strain appears to be anticipated by the aforementioned reference.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ruth A. Davis  
November 19, 2004  
AU 1651

A handwritten signature in black ink, appearing to read "R. Davis".